FEB 1 5 2001

510(k) Summary
for the Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets

K 003549

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person

James M. Flaherty, Jr., RAC
Regulatory Affairs Specialist
Telephone Number: (508) 880-8404
Fax Number: (508) 828-3212

Name of Device

Proprietary Name:	Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets
Common Name:	Craniofacial absorbable fixation system rivets
Classification Name:	Cranioplasty plate fasteners

Device Classification

These devices have been placed in Class II for cranioplasty plate fasteners per 21 C.F.R. § 882.5360 (84HBW).

Statement of Substantial Equivalence

The Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets are substantially equivalent to the Codman CRANIOSORB™ Absorbable Fixation System Clear Rivets based on the subject devices' similarity to the predicate devices in intended use, materials, design, and principles of operation.

Indications for Use

The Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets are intended for use as part of the Codman CRANIOSORB™ Absorbable Fixation System to secure CRANIOSORB™ plates and meshes to bone.

Physical Description

The CRANIOSORB™ Purple Rivets are identical to the CRANIOSORB™ Clear Rivets in all respects with the exception that D&C Violet No. 2 dye has been added to the CRANIOSORB™ Purple Rivets for increased visualization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James M. Flaherty
Regulatory Affairs Specialist
Codman & Shurtleff, Inccorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K003549
Trade Name: Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets
Regulatory Class: II
Product Code: JEY
Dated: November 16, 2000
Received: November 17, 200

Dear Mr. Flaherty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K003549

Device Name **Codman CRANIOSORB™ Absorbable Fixation System Purple Rivets**

Indications For Use:

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(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K003549